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Sheet 1 of 1

Form PTO-1449

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U.S. PATENT DOCUMENTS

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<i>RV</i>	US 20 02 01 07 38 8 A1	08/08/02	Vandenbark	—	—	

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation
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1614 1644

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
RV	US 3 8 4 9 5 5 0	11/19/74	Teitelbaum et al.	—	—	
	US 4 3 3 9 4 3 1	7/13/82	Gaffar	—	—	
	US 5 2 0 4 0 9 9	4/20/93	Barbier et al.	—	—	
	US 5 5 9 1 6 2 9	1/7/97	Rodriguez et al.	—	—	
	US 5 6 2 7 2 0 6	5/6/97	Hupe et al.	—	—	
	US 5 6 6 8 1 1 7	9/16/97	Shapiro et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
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RV	WO 8 8 1 0 1 2 0	12/29/88	US	—	—		
	WO 9 5 3 1 9 9 0	11/30/95	US	—	—		
	WO 9 5 3 3 4 7 5	12/14/95	Europe	—	—		
	WO 9 8 3 0 2 2 7	7/16/98	US	—	—		
	WO 0 0 0 5 2 5 0	2/3/00	US	—	—		
	WO 0 0 1 8 7 9 4	4/6/00	US	—	—		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

RV	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", <u>Eur. J. Immunol.</u> , 1971, <u>1</u> , 242-248
	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide", <u>Israel J. Med. Sci.</u> , 1971, <u>7</u> , 630-631 (Abstract)
	Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Copolymer Immunological Cross Reactive with Basic Encephalitogen", <u>Israel J. Med. Sci.</u> , 1972, <u>8</u> , 1759-1760
	Teitelbaum, et al., "Protection Against Experimental Allergic Encephalomyelitis", <u>Nature</u> , 1972, <u>240</u> , 564-566
	Webb, et al., "Further Studies on the Suppression of Experimental Allergic Encephalomyelitis by Synthetic Copolymer", <u>Israel J. Med. Sci.</u> , 1972, <u>8</u> , 656-657
	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis with Basic Polymers", <u>Eur. J. Immunol.</u> , 1973, <u>3</u> , 273-279

EXAMINER

DATE CONSIDERED

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R	US 5 7 1 9 2 9 6	2/17/98	Acton III, et al.	—	—	
	US 5 8 0 0 8 0 8	9/1/98	Konfino et al.	—	—	
	US 5 8 5 8 9 6 4	1/12/99	Aharoni et al.	—	—	
	US 5 9 8 1 5 8 9	11/9/99	Konfino et al.	—	—	
	US 5 9 5 8 9 7 2	9/28/99	Hupe et al.	—	—	
	US 6 0 4 8 8 9 8	4/11/00	Konfino et al.	—	—	
	US 6 0 5 4 4 3 0	4/25/00	Konfino et al.	—	—	
	US 6 2 1 4 7 9 1	4/10/01	Arnon et al.	—	—	
	US 6 3 4 2 4 7 6	1/29/02	Konfino et al.	—	—	

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation	
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R WO 0 0 2 0 0 1 0	4/13/00	US	—	—		
WO 0 0 2 7 4 1 7	5/18/00	US	—	—		
WO 0 0 0 5 2 4 9	2/3/00	US	—	—		
WO 0 0 2 0 0 1 0	4/13/00	US	—	—		
WO 0 1 6 0 3 9 2	8/23/01	US	—	—		
WO 0 1 9 3 8 2 8	12/13/01	US	—	—		
WO 0 1 9 7 8 4 6	12/27/01	US	—	—		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

R	Webb, et al., "In Vivo and in Vitro Immunological Cross-reactions between Basic Encephalitogen and Synthetic Basic Polypeptides Capable of Suppressing Experimental Allergic Encephalomyelitis", <u>Eur. J. Immunol.</u> , 1973, 3, 279-286
	Teitelbaum, et al., "Dose-response Studies on Experimental Allergic Encephalomyelitis Suppression by COP-1", <u>Israel J. Med. Sci.</u> , 1974, 10(9), 1172-1173
	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", <u>Clin. Immunol. Immunopath.</u> , 1974, 3, 256-262
	Webb, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", <u>Isr. J. Med. Sci.</u> , 1975, 11, 1388 (Abstract)

EXAMINER

DATE CONSIDERED

7/10/03

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—	US 09 3 5 9 0 9 9	7/22/99	Strominger et al.			
—	US 09 4 0 5 7 4 3	9/24/99	Gad et al.			
—	US 09 7 6 8 8 7 2	1/23/01	Aharoni et al.			
—	US 09 8 1 6 9 8 9	3/23/01	Gad et al.			
—	US 09 8 7 5 4 2 9	6/5/01	Yong and Chabot.			
—	US 09 8 8 5 2 2 7	6/20/01	Rodriguez and Ure.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
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<i>R</i>	EP 0 3 8 3 6 2 0	8/22/90	Europe	—	—		
<i>R</i>	EP 0 3 5 9 7 8 3	11/29/95	Europe	—	—		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>82</i>	Webb, et al., "Molecular Requirements Involved in Suppression of EAE by Synthetic Basic Copolymers of Amino Acids", <u>Immunochem.</u> , 1976, <u>13</u> , 333-337
	Abramsky, et al., "Effect of a Synthetic Polypeptide (COP-1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis", <u>J. Neurol. Sci.</u> , 1977, <u>31</u> , 433-438
	Teitelbaum, et al., "Suppression of Experimental Allergic Encephalomyelitis in Baboons by Cop 1", <u>Israel J. Med. Sci.</u> , 1977, <u>13</u> , 1038 (Abstract)
	Arnon, et al., "Suppression of EAE in Baboons by a Synthetic Polymer of Amino Acids", <u>Neurol.</u> , 1978, <u>28</u> , 336 (Abstract)
	Sela, et al., "Experimental Allergic Encephalomyelitis" in <u>Menarini Series on Immunopathology</u> , vol. 1, <u>First Symposium of Organ Specific Autoimmunity</u> , Cremona, Italy, June, 1977, (Miescher P.A. ed., Schwabe Co., Basel, 1978), 9-21
	Alvord, et al., "Myelin Basic Protein Treatment of Experimental Allergic Encephalomyelitis in Monkeys", <u>Ann. Neurol.</u> , 1979, <u>6</u> , 469-473
	Keith, et al., "The Effect of COP 1, a Synthetic Polypeptide, on Chronic Relapsing Experimental Allergic Encephalomyelitis in Guinea Pigs" <u>J. Neurol. Sci.</u> , 1979, <u>42</u> , 267-274
	Lando, et al., "Effect of Cyclophosphamide on Suppressor Cell Activity in Mice Unresponsive to EAE", <u>J. Immunol.</u> , 1979, <u>123</u> , 2156-2160 (Abstract)

EXAMINER

DATE CONSIDERED

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1614 / 644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Lando, et al., "Experimental Allergic Encephalomyelitis in Mice - Suppression and Prevention with COP-1", Israel J. Med. Sci., 1979, 15, 868-869 (Abstract)

Teitelbaum, et al., "Blocking of Sensitization to Encephalitogenic Basic Protein in Vitro by Synthetic Basic Copolymer (COP 1)" in Cell Biology and Immunology of Leukocyte Function (Academic Press, New York, 1979) 681-685

Teitelbaum, "Suppression of Experimental Allergic Encephalomyelitis with a Synthetic Copolymer - Relevance to Multiple Sclerosis", in Humoral Immunity in Neurological Diseases (Karcher D., Lowenthal A. & Strosberg A.D., eds., Plenum Publishing Corp., 1979) 609-613

Arnon, et al., "Desensitization of Experimental Allergic Encephalomyelitis with Synthetic Peptide Analogues" in The Suppression of Experimental Allergic Encephalomyelitis and Multiple Sclerosis (Academic Press, New York, 1980) 105-107

Arnon, "A Synthetic Copolymer of Amino Acids in a Clinical Trial for MS Therapy" in Progress in Multiple Sclerosis Research (Bauer, Ritter, eds., Springer Verlag New York, 1980) 416-418

Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", Ann. Neurol., 1980, 8, 117 (Abstract)

Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", Trans. Am. Neurol. Assoc., 1980, 105, 348-350

McDermott, et al., "Antigen-induced Suppression of Experimental Allergic Neuritis in the Guinea Pig", J. Neurol. Sci., 1980, 46, 137-143

Arnon, "Experimental Allergic Encephalomyelitis - Susceptibility and Suppression", Immunological Rev., 1981, 55, 5-30

Bornstein, et al., "Multiple Sclerosis: Trial of a Synthetic Polypeptide", Ann. Neurol., 1982, 11, 317-319

Brosnan, et al., "The Response of Normal Human Lymphocytes to Copolymer 1", J. Neuropath. Exp. Neurol., 1983, 42, 356 (Abstract)

Lisak, et al., "Effect of Treatment with Copolymer 1 (Cop-1) on the in Vivo and in Vitro Manifestations of Experimental Allergic Encephalomyelitis (EAE)", J. Neurol. Sci., 1983, 62, 281-293

Bornstein, et al., "Clinical Trials of Copolymer 1 in Multiple Sclerosis", Ann. N.Y. Acad. Sci. (USA), 1984, 366-372

EXAMINER

DATE CONSIDERED

7/10/03

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Group Art Unit

1614-1644

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Bornstein, et al., "Clinical Trials of a Synthetic Polypeptide (Copolymer 1) for the Treatment of Multiple Sclerosis" in Gonsett et al., Immunological and Clinical Aspects of Multiple Sclerosis (MTP Press, The Hague, 1984) 144-150

Brosnan, et al., "Copolymer 1: Effect on Normal Human Lymphocytes", Ann. N.Y. Acad. Sci. (USA), 1984, 436, 498-499

Bornstein, et al., "Multiple Sclerosis: Clinical Trials of a Synthetic Polypeptide, Copolymer 1", Neurol., 1985, 35 (Suppl. 1), 103 (Abstract)

Brosnan, et al., "Immunogenic Potentials of Copolymer 1 in Normal Human Lymphocytes", Neurol., 1985, 35, 1754-1759

Burns, et al., "Human Cellular Immune Response in Vitro to Copolymer 1 and Myelin Basic Protein (MBP)", Neurol., 1985, 35 (Suppl. 1), 170 (Abstract)

Teitelbaum, et al., "Monoclonal Antibodies to Myelin Basic Protein Cross React with Synthetic EAE-suppressive Copolymer, COP 1" in Proc. 7th Eur. Immunol. Mtg., Jerusalem, September 8-13, 1985 (Abstract)

Thompson, "MCQ Tutor: Medical Immunology Multiple Choice Questions", Immunol. Today, 1985, 6(4), 141

Burns, et al., "Human Cellular Immune Response to Copolymer 1 and Myelin Basic Protein", Neurol., 1986, 36, 92-94

Bornstein, "Cop 1 May be Beneficial for Patients with Exacerbating-remitting Form of Multiple Sclerosis", Adv. Ther. (USA), 1987, 4, 206 (Abstract)

Bornstein, et al., "A Pilot Trial of Cop 1 in Exacerbating-remitting Multiple Sclerosis", New Eng. J. Med., 1987, 317(7), 408-414

Rolak, "Copolymer-I Therapy for Multiple Sclerosis", Clin. Neuropharmacology, 1987, 10(5), 389-396

Winer, "COP 1 Therapy for Multiple Sclerosis", New Eng. J. Med., 1987, 317(7), 442-444

Arnon, et al., "Suppression of Demyelinating Diseases by Synthetic Copolymers", in A Multidisciplinary Approach to Myelin Disease (G. Serlupi Crescenzi, ed., Plenum Publishing Corp., 1988) 243-250

Baumhefner, et al., "Copolymer 1 as Therapy for Multiple Sclerosis: The Cons", Neurol., 1988, 38(Suppl. 2), 69-71

Bornstein, et al., "Clinical Experience with COP-1 in Multiple Sclerosis", Neurol., 1988, 38(Suppl. 2), 66-69

EXAMINER

DATE CONSIDERED

7/10/03

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Teitelbaum, et al., "Specific Inhibition of the T-cell Response to Myelin Basic Protein by the Synthetic Copolymer Cop 1", Proc. Natl. Acad. Sci. USA, 1988, 85, 9724-9728

Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by Cop-1 - Relevance to Multiple Sclerosis", Israel J. Med. Sci., 1989, 25, 686-689

Bornstein, et al., "Pilot Trial of COP-1 in Chronic Progressive Multiple Sclerosis: Preliminary Report", from The International Multiple Sclerosis Conference: An Update on Multiple Sclerosis, Roma (Italy), September 15-17, 1988, in Elsevier Science Publisher, 1989, 225-232

Teitelbaum, et al., "Clinical Trial of Copolymer 1 in Multiple Sclerosis" J. Israel Med. Assoc., 1989, CXVI(9), 453-456

Bornstein, et al., "Clinical Trials of Cop 1 in Multiple Sclerosis" in Handbook of Multiple Sclerosis (S.D. Cook Marcel Rekker, ed., 1990) 469-480

Carter, et al., "Newer Drug Therapies for Multiple Sclerosis", Drug Therapy, 1990, 31-32, 37-39, 42-43

Grgacic, et al., "Cell-mediated Immune Response to Copolymer 1 in Multiple Sclerosis Measured by the Macrophage Procoagulant Activity Assay", Int. Immunol., 1990, 2(8), 713-718

Kay, et al., "The Mechanism of Action of FK 506", Transplantation Proceedings, 1990, 22(1, Suppl. 1), 96-99

Lee, et al., "Peptide and Protein Drug Delivery" in Advances in Parenteral Sciences (Vincent H.L. Lee, ed., Marcel Dekker, Inc., 1990) 691-695

Myers, et al., "The Peculiar Difficulties of Therapeutic Trials for Multiple Sclerosis", Neurologic Clinics, 1990, 8(1), 119-141

Sela, et al., "Suppressive Activity of COP-1 in EAE and its Relevance to Multiple Sclerosis", Bull. Inst. Pasteur, 1990, 88, 303-314

Starzl, Transplantation Proceedings, 1990, 22(1, Suppl. 1), 5

Wender, "Copolymer 1 (COP-1) in the Treatment of Multiple Sclerosis (letter)" Neur. Neurochir. Pol., 1990, 24, 113

Bornstein, et al., "A Placebo-controlled, Double-blind, Randomized Two-center, Pilot Trial of Cop 1 in Chronic Progressive Multiple Sclerosis", Neurol., 1991, 41, 533-539

Burns, et al., "Failure of Copolymer 1 to Inhibit the Human T-cell Response to Myelin Basic Protein", Neurol., 1991, 41, 1317-1319

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AV Clinical Trial Protocol No. 9001, Teva Pharmaceutical Industries, Ltd., first patient enrolled October 23, 1991

1 Ferrara, et al., "Graft-Versus-Host Disease", New Eng. J. Med., 1991, 324, 667-674

Meiner, "COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple-Sclerosis: One Year Follow-up", J. Neurol., 1991(Suppl. 1) (Abstract)

Rothbard, et al., "Interactions Between Immunogenic Peptides and MHC Proteins", Ann. Rev. Immunol., 1991, 9, 527-565

Salvetti, et al., "Myelin Basic Protein T Cell Epitopes in Patients with Multiple Sclerosis", Department of Neurological Sciences, University of Rome, La Sapienza 1991, 72 (Abstract)

Teitelbaum, et al., "Cross-reactions and Specificities of Monoclonal Antibodies Against Myelin Basic Protein and Against the Synthetic Copolymer 1", Proc. Natl. Acad. Sci. (USA), 1991, 88, 9528-9532

Van den Bogaerde, et al., "Induction of Long-Term Survival of Hamster Heart Xenografts in Rats", Transplantation, 1991, 52, 15-20

Bornstein, et al., "Treatment of Multiple Sclerosis with Copolymer 1" in Treatment of Multiple Sclerosis: Trial Design, Results and Future Perspectives (Rudick R.A. & Goodkin D.E., eds., Springer Verlag, London, 1992) 173-198

Johnson, "Clinical Studies in Copolymer 1 Therapy for Exacerbating-remitting Multiple Sclerosis", in Congress for Advances in the Understanding and Treatment of Multiple Sclerosis, Boston (USA), Oct. 28-29, 1992

Milo, et al., "Inhibition of Myelin Basic Protein-specific Human T-cell Lines by COP-1", Israel J. Med. Sci., 1992, 28, 486 (Abstract)

Racke, et al., "Copolymer-1-induced Inhibition of Antigen-specific T Cell Activation: Interference with Antigen Presentation", J. Neuroimmunol., 1992, 37, 75-84

Teitelbaum, et al., "Synthetic Copolymer 1 Inhibits Human T-cell Lines Specific for Myelin Basic Protein", Proc. Natl. Acad. Sci. (USA), 1992, 89, 137-141

Weinshenker et al., "Natural History and Treatment of Multiple Sclerosis", Current Opinion in Neurol. and Neurosurgery, 1992, 5, 203-211

EXAMINER

DATE CONSIDERED

7/10/03

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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1614/644INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- Aharoni, et al., "T Suppressor Hybridomas and Interleukin-2-Dependent Lines Induced by Copolymer 1 or by Spinal Cord Homogenate Down-Regulate Experimental Allergic Encephalomyelitis", Eur. J. Immunol., 1993, 23, 17-25
- Arnon, et al., "Immunomodulation of Experimental Allergic Encephalomyelitis", Israel J. Med. Sci., 1993, 29, 175-181
- Arnon, et al., "On the Existence of Suppressor Cells", Int. Arch. Allergy Immunol., 1993, 100, 2-7
- Clinical Trial Protocol No. 9002, Lemmon Co. and Teva Pharmaceutical Industries, Ltd., first patient enrolled June 17, 1993
- Francis, "The Current Therapy of Multiple Sclerosis", J. Clin. Pharmacy and Therapeutics, 1993, 18, 77-84
- Keleman, et al., "Graft-versus-Host Disease in Bone Marrow Transplantation: Experimental, Laboratory, and Clinical Contributions of the Last Few Years", Int. Arch. Allergy Immunol., 1993, 102, 309-320
- Gurevich, "Study of the MHC-competition Between BP and Cop 1 Using Human Cytotoxic T-cell Clones", Israel J. Med. Sci., 1993 (Abstract)
- Meiner, et al., "The Israeli COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple Sclerosis - Two-year Follow-up", in 9th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, Florence (Italy), October-November, 1993, 48 (Abstract)
- Milo, et al., "Copolymer-1 (COP-1) Regulates Class II MHC Expression and Cytokine Synthesis in the THP-1 Monocyte-Macrophage Cell Line" in The IBC Conference on Multiple Sclerosis, San Diego (USA), December 10, 1993 (Abstract)
- Sela, "Polymeric Drugs as Immunomodulatory Vaccines Against Multiple Sclerosis", Makromol. Chem. Macromol. Symp., 1993, 70/71, 147-155
- Arnon, et al., "Immunospecific Drug Design - Prospects for Treatment of Autoimmune Disease", Therapeutic Immunol., 1994, 1, 65-70
- Bansil, et al., "Multiple Sclerosis: Pathogenesis and Treatment", Seminars in Neurol., June 1994, 14(2), 146-153
- The COP-1 Multicenter Clinical and Research Group Study, "COP-1 Multicenter Trial in Relapsing Remitting Multiple Sclerosis: 3 Year Follow Up", Abstracts of Symposia and Free Communication, Barcelona (Spain), June 25-29, 1994, 241 (Suppl. 1), 6
- Cotton, "Options for Multiple Sclerosis Therapy", J.A.M.A. Medical News & Perspectives, 1994, 272(18), 1393

EXAMINER

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(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Dorling, et al., "Prospects for Xenografting", Curr. Opinions Immunol., 1994, 6, 765-769

Fridkis-Hareli, et al., "Copolymer 1 Displaces MBP, PLP and MOG, but Can Not be Displaced by these Antigens from the MHC Class II Binding Site", Department of Chemical Immunology, The Weizmann Institute of Science, 1994

Fridkis-Hareli, et al., "Direct Binding of Myelin Basic Protein and Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells - Specificity and Promiscuity", Proc. Natl. Acad. Sci. USA, 1994, 91, 4872-4876

Fridkis-Hareli, et al., "Specific and Promiscuous Binding of Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", Israeli Biochem. Soc., 1994, 21-22 (Abstract)

Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells" in Neurochem Mtg., August 14-19, 1994

Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen- Presenting Cells", J. Neurochem., 1994, 63 (Suppl. I), 561

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Undergo Processing Prior to the Binding to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells", Israeli Immunol. Soc., May 3-4, 1994 (Abstract)

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein do not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", Department of Chemical Immunology, The Weizmann Institute of Science, Rehovot, Israel, 1994,

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells", Cell. Immunol., 1995, 163, 229-236

Jacobs et al., "Advances in Specific Therapy for Multiple Sclerosis", Neurol., 1994, 7, 250-254

EXAMINER

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INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- Johnson, "Experimental Therapy of Relapsing-Remitting Multiple Sclerosis with Copolymer-1", Ann. Neurol., 1994, 36(Suppl.), 115-117
- Kott, et al., "COP-1 Increases Suppressor Cells Number in Multiple Sclerosis", Israel Neurological Assoc., December 19-20, 1994, Herzliya (Israel), 17
- Mengle-Gaw, "The Major Histocompatibility Complex (MHC)", in Encycl. Molecular Bio. (Oxford Blackwell Science Ltd, 1994) 602-606
- Milo, et al., "Additive Effects of COP-1 and IFN-Beta on Immune Responses to Myelin Basic Protein", Neurol., 1994, 44(Suppl. 2), A212
- Milo, et al., "Additive Effect of Copolymer-1 and Interferon- β on the Immune Response to Myelin Basic Protein", Assaf Harofeh Medical Center, Sackler School of Medicine, Tel-Aviv University of Maryland School of Medicine, 1994, 22
- Milo, et al., "Copolymer-1 and Interferon- β Additively Suppress the Immune Response to Myelin Basic Protein by Inhibiting Antigen Presentation", J. Neuroimmunol., 1994, 54, 183 (Abstract)
- Nightingale, et al., "Access to Investigational Drugs for Treatment Purposes", Am. Family Physician, 1994, 50(4), 845-847
- Schlegel, et al., "Prevention of Graft-Versus-Host Disease by Peptides Binding to Class II Major Histocompatibility Complex Molecules", Blood, 1994, 84(8), 2802-2810
- Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", Ann. Neurol., 1994, 36, 114-115
- Teitelbaum, et al., "Immunological Parameters in a Multicenter Clinical Trial of COP1 in Multiple Sclerosis (MS): A 2-year Follow-up", Neurol., 1994, 44(Suppl. 2), A358
- Tisch et al., "Antigen-specific immunotherapy: Is it a Real Possibility to Combat T-Cell-Mediated autoimmunity?" Proc. Natl. Acad. Sci. U.S.A., 1994, 91, 437-438
- Milo, et al., "Additive Effects of Copolymer-1 and Interferon β -1b on the Immune Response to Myelin Basic Protein", J. Neuroimmunol., 1995, 61, 185-193
- O'Connor, et al., "Powders" in The Science and Practice of Pharmacy, Remington, 1995, 2, 1598-1614
- Porter, "Coating of Pharmaceutical Dosage Forms," in The Science and Practice of Pharmacy, Remington, 1995, 2, 1650-1659

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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1614 1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- Reilly, Jr., W.J., "Pharmaceutical Necessities" in The Science and Practice of Pharmacy, Remington, 1995, 2, 1380-1416
- Schlegel, et al., "Inhibition of Allorecognition and Prevention of Graft-vs-host Disease (GVHD) by GLAT, a Synthetic Polymer with Promiscuous Binding to Murine and Human MHC Class II Molecules", in Am. Soc. Hematology, 37th Annual Meeting, Seattle, WA (USA), December 1-5, 1995, 224a (Abstract)
- Ben-Nun, et al., "The Autoimmune Reactivity to Myelin Oligodendrocyte Glycoprotein (MOG) in Multiple Sclerosis is Potentially Pathogenic: Effect of Copolymer 1 on MOG-induced Disease", J. Neurol., 1996, 243 (Suppl. 1), S14-S22
- Johnson, Management of Relapsing/Remitting Multiple Sclerosis with Copolymer 1 (Copaxone)", Chemical Abstracts, 1996, 125, 291993b
- Sykes, "Immunobiology of Transplantation", Faseb J., 1996, 10, 721-730
- Teitelbaum, et al., "Copolymer 1 Inhibits Chronic Relapsing Experimental Allergic Encephalomyelitis Induced by Proteolipid Protein (PLP) Peptides in Mice and Interferes with PLP-specific T Cell Responses", J. Neuroimmunol., 1996, 64, 209-217
- Aharoni, et al., "Studies on the Mechanism and Specificity of the Effect of the Synthetic Random Copolymer GLAT on Graft-versus-Host Disease", Immunol. Letters, 1997, 58, 79-87
- Puri et al., "Modulation of the Immune Response in Multiple Sclerosis", J. Immunol., 1997, 158, 2471-2476
- Tarcic et al., "Copolymer 1 (Copaxone) from an Idea to a Drug for Treatment of Multiple Sclerosis" Database HCAPLUS on STN, Israel: AN 1997:333270. Kim, Handasa Kim, 1997, 281(14), 16-18 (Abstract)
- Teitelbaum, et al., "Copolymer 1 from the Laboratory to FDA", Israel J. Med. Sci., 1997, 33, 280-284
- Fridkis-Hareli, et al., "Promiscuous Binding of Synthetic Copolymer 1 to Purified HLA-DR Molecules", J. Immunol., 1998, 160, 4386-4397
- Fridkis-Hareli, et al., "Synthetic Amino Acid Copolymers that Bind to HLA-DR Proteins and Inhibit Type II Collagen-reactive T Cell Clones", Proc. Natl. Acad. Sci., October 1998, 95, 12528-12531
- Cazzato, et al., "Treatment of Multiple Sclerosis. The Present and the Future. Study Group on Diagnosis and Therapy of Multiple Sclerosis", Database Medline on STN, Instituto do Clinica Neurologica, Universita, Trieste, Italy: Medline AN: 2000060325, Recent Progressi in Medicina. October 1999, 90(10), 538-544 (Abstract)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Group Art Unit

1614 1644

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AV | Kepsutlu et al., "Evaluation of Chitosan Used as an Excipient in Tablet Formulations", Database HCAPLUS on STN, Department of Pharmaceutical Technology, Gulhane Military Medical Academy, Ankara, 06018, Turkey, HCAPLUS AN: 1999: 590411, Acta. Pol. Pharm. 1999, 56(3), 227-235 (Abstract)

| Prat, et al., "Lymphocyte Migration and Multiple Sclerosis: Relation with Disease Course and Therapy," Ann. Neurol., 46, 253-256 (1999)

| Fridkis-Hareli et al., "Synthetic Peptides that Inhibit Binding of the Collagen Type II 261-273 Epitope to Rheumatoid Arthritis-Associated HLA-DR1 and DR4 Molecules and Collagen-Specific T-cell Responses", Database HCAPLUS on STN, Department of Clinical Immunology, Aarhus University Hospital, Aarhus, Denmark, HCAPLUS AN: 2000:455053, Human Immunology, 2000, 61(7), 640-650 (Abstract)

| Durelli, "Immunotherapeutics of Multiple Sclerosis", Istituto di Clinica delle Malattie del Sistema Nervoso Università di Torino, 467-475

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DATE CONSIDERED

7/10/03

*EXAMINER Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.